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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,125	10/21/2003	Pierpaolo Correale	126442-100008-US	5287

34026 7590 01/03/2006

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/691,125

Applicant(s)

CORREALE ET AL.

Examiner

Agnes B. Rooke

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 and 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>May 6, 2005</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

Applicant's election with traverse of Group I, claims 1-8, 18, and 19, in the reply filed on 10/19/2005 is acknowledged. The Applicant did not provide any arguments for the traversal. Therefore, the restriction requirement is FINAL.

Claims 9-17 and 20-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP paragraph 821.01.

This application claims priority of 60/420,165, filed on 10/21/2002.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, Applicants refer to an immunostimulatory fragment of the amino acid sequence of SEQ ID NO:1 or a functional variant of SEQ ID NO:1 comprising one or more amino acid additions, substitutions or deletions. A fragment of a peptide could be

a single amino acid such as an amino acid lysine, for example. There is no disclosure of which fragments might have immunostimulatory activity, nor is there a disclosure of which part of SEQ ID NO:1 is responsible for that activity. Thus, there is no correlation between the structure of any fragments and their possible stimulatory function.

Applicants also claim functional variants of SEQ ID NO:1. As to this matter, there are virtually an infinite number of such variants that do not necessary resemble SEQ ID NO:1 in any way, and thus, the undisclosed structure of the claimed functional variants do not correspond with their function. Applicants are clearly not in possession of any and all variants.

Claim 2 does not satisfy the written description requirement with regard to the functional variants of SEQ ID NOs:2, 3, 4 or 5 for the same reasons as above.

Claims 3 and 4 do not satisfy the written description requirement for the same reasons as claim 1 and also because the structure of a "helper epitope" is not provided, and thus Applicants cannot be in possession of all helper epitopes.

Claims 18 and 19 are included in this rejection because they claim a kit composed of the PTH-rP peptide and instructions for use. However, the instructions for use do not cure the lack of adequate written description of claim 1.

Claims 1-8 and 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable a person skilled in the art to which it pertains, or with which it is mostly connected, to make or use the invention commensurate in scope with these claims. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are: 1) the nature of the invention, 2) the breadth of the claims, 3) the state of the prior art, 4) the predictability or lack thereof in the art, 5) the amount of direction or guidance present, 6) the presence or absence of working examples, 7) the quantity of experimentation needed, and 8) the level of the skill in the art.

1) The nature of the invention: the invention relates to an immunostimulatory PTH-rP peptide comprising a fragment of the amino acid sequence of SEQ ID NO:1 or a functional variant thereof comprising one or more amino acid additions, substitutions or deletions;

2) the breadth of the claims: claims are broad because they claim any fragment of SEQ ID NO:1 or a functional variant thereof, which comprises unidentified mutations, such additions, substitutions or deletions;

3) the state of the prior art: different isoforms of PTH-rP peptide are known in the prior art;

4) the predictability or unpredictability of the art: the art is unpredictable because the change in the structure of the protein might alter the function of the protein in

unpredictable way; thus the unpredictability of the effect each change will have on the function of the protein carries over to the whole protein;

5) the amount of direction or guidance present: there is no guidance provided regarding all different fragments of SEQ ID NO:1 or functional variants thereof comprising one or more amino acid additions, or substitutions or deletions; the only two PTH-rP derived peptides that Applicants refer to in their experiments are PTR-2 and PTR-4 in [0126], [0134], [0136];

6) the presence or absence of working examples: there are no working examples that would encompass all different fragments of SEQ ID NO:1 or functional variants thereof comprising one or more amino acid additions, substitutions or deletions; the only two PTH-rP derived peptides PTR-2 and PTR-4 mentions in working examples are in paragraphs [0126], [0134], and [0136], for example;

7) the quantity of experimentation necessary: there would be an infinite amount of experimentation necessary to determine, and characterize all possible different fragments of SEQ ID NO:1 or functional variants thereof comprising one or more amino acid additions, substitutions or deletions; thus it would be impossible to essay for all these fragments and functional variants; also, on page 14 of the specification Applicants state that the PTH-rP fragment could be as short as 8 amino acids or as long as 30 amino acids, thus the claimed invention is unpredictable; an infinite amount of experimentation would be necessary to characterize all the fragments or functional fragments with different unknown mutations

8) the relative skill of those skilled in the art: the skill in the art is a person with a graduate degree in the art;

In consideration of the *In re Wands* factors 1-8, it is apparent that undue experimentation would be to practice the claimed invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The kit in claims 18 and 19 is not defined at all, therefore these claims are indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

All rejections have been made based on the USPTO search engine GenCore version 5.1.6.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bagnoli et al. (U.S. 5,880,093). **SEQ ID NO:1** of the instant application is disclosed in columns 9 and 10 as SEQ ID NO:5 in Bagnoli et al.

Claims 1, 2, 5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 822 200 A1. **SEQ ID NO:2** is disclosed in claim 10, on page 67 in EP 0 822 200 A1.

Claims 1, 2, 5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenblatt et al. (U.S. 5,114,843). **SEQ ID NO:3** is disclosed in claim 2, column 8 in the Rosenblatt et al.

Claims 1, 2, 5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/69900. **SEQ ID NO:4** and **SEQ ID NO:5** are disclosed on pages 105 and 106 as SEQ ID NO:305 in WO 00/69900.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagnoli et al. in view of Yoneda et al.



Bagnoli et al. teachings are described regarding SEQ ID NO:1. Bagnoli et al. do not teach a helper epitope in a composition with PTH-rP.

Yoneda et al. teach anti-PTH-rP that can be prepared in a variety of ways; where a suitable immunogen, such as PTH-rP or a subunit is administered to a vertebrate-capable of an immune response to the immunogen; where particularly preferred subunits of PTH-rP include those in the N-terminal region, in particular positions 1-34; and where the PTH-rP or subunit used as immunogen should include epitopes characteristic of the particular species PTH-rP for which antibodies are described. See column 6, lines 1-11.

Therefore, it would have been obvious to one of an ordinary skill in the art at the time the invention was made to design a peptide of SEQ ID NO:1 as taught by Bagnoli et al. which comprises a helper epitope as taught by Yoneda et al.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0822200 A1 in view of Yoneda et al.

EP 0822200A1 discloses SEQ ID NO:2. See above. The reference does not teach a helper epitope.

Yoneda et al. teach epitope of PTH-rP. See above.

Therefore, it would have been obvious to one of an ordinary skill in the art at the time the invention was made to design a peptide of SEQ ID NO:2 as taught in EP 0822200A1 which comprises a helper epitope as taught by Yoneda et al.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblatt et al. in view of Yoneda et al.

Rosenblatt et al. disclose SEQ ID NO:3 See above. The reference does not teach a helper epitope.

Yoneda et al. teach epitope of PTH-rP. See above.

Therefore, it would have been obvious to one of an ordinary skill in the art at the time the invention was made to design a peptide of SEQ ID NO:3 as taught by Rosenblatt et al. which comprises a helper epitope as taught by Yoneda et al.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/69900 in view of Yoneda et al.

WO 00/69900 discloses SEQ ID NO:4 and SEQ ID NO:5 See above. The reference does not teach a helper epitope.

Yoneda et al. teach epitope of PTH-rP. See above.

Therefore, it would have been obvious to one of an ordinary skill in the art at the time the invention was made to design a peptide of SEQ ID NO:4 and 5 as taught by WO 00/69900 which comprises a helper epitope as taught by Yoneda et al.

Claim 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagnoli et al.

Teachings of Bagnoli et al. are disclosed above, where he discloses SEQ ID NO:1.

It would have been obvious to one of an ordinary skill in the art at the time the invention was made to design SEQ ID NO:1, for example, as taught by Bagnoli et al. and place few of these peptides together in a composition.

Claim 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagnoli et al. in view of Yoneda et al.

Teachings of Bagnoli et al. are disclosed above, where he disclose SEQ ID NO:1.

Teaching of Yoneda et al. are disclosed above, where he teach epitope of PTH-rP.

It would have been obvious to one of an ordinary skill in the art at the time the invention was made to design SEQ ID NO:1, for example, as taught by Bagnoli et al. and place few of these peptides together in a composition where the multiepitope peptide comprises a helper epitope as taught by Yoneda et al.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagnoli et al (for SEQ ID NO:1), EP 0822200 A1 (for SEQ ID NO:2), Rosenblatt et al. (for SEQ ID NO:3), and WO 00/699900 (for SEQ ID NO:4 and 5).

The teachings of the references are described above, where the compositions of SEQ ID NO:1, 2, 3, 4, and 5 in claims 1 and 2 are disclosed.

Therefore it would have been obvious to one of an ordinary skill in the art at the time the invention was made to design a kit, which contains these compositions. The instructions to the kit are not patentable by themselves.

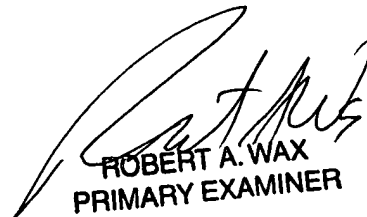
### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

  
ROBERT A. WAX  
PRIMARY EXAMINER